

WHAT IS CLAIMED IS:

1           1. A method for remodeling luminal tissue, said method comprising:  
2           positioning a vibrational transducer at a target site in a body lumen of a  
3 patient; and  
4           energizing the vibrational transducer to produce acoustic energy under  
5 conditions selected to induce tissue remodeling in at least a portion of the tissue  
6 circumferentially surrounding the body lumen.

1           2. A method as in claim 1, wherein the acoustic energy is produced under  
2 conditions which at least shrink the tissue.

1           3. A method as in claim 1, wherein the acoustic energy is produced under  
2 conditions which reduces the compliance of the tissue in either or both the radial and  
3 longitudinal directions.

1           4. A method as in claim 1, wherein the acoustic energy is produced under  
2 conditions which at least induce collagen formation in the tissue.

1           5. A method as in claim 1, wherein the acoustic energy is produced under  
2 conditions which at least cause cavitation in the tissue.

1           6. A method as in claim 1, wherein the acoustic energy is produced under  
2 conditions which at least interrupt nerve pathways in the tissue.

1           7. A method as in claim 1, wherein the acoustic energy is produced under  
2 conditions which at least interrupt the reception and/or production of biochemicals in the  
3 tissue.

1           8. A method as in claim 1, wherein the acoustic energy is produced under  
2 conditions which at least interrupt the ability of the tissue to absorb food.

1           9. A method as in claim 1, wherein the acoustic energy is produced under  
2 conditions which at least selectively destroy intestinal metaplasia in the esophagus.

1           10. A method as in claim 1, wherein the transducer is energized to produce  
2 acoustic energy in the range from 10 W/cm<sup>2</sup> to 100 W/cm<sup>2</sup>.

1               11. A method as in claim 1, wherein the transducer is energized at a duty  
2 cycle from 10 % to 100 %.

1               12. A method as in claim 1, wherein the transducer is energized under  
2 conditions which heat the tissue to a temperature in the range from 55°C to 95°C.

1               13. A method as in claim 1, further comprising cooling the luminal surface  
2 tissue while tissue beneath the surface is heated.

1               14. A method as in claim 1, wherein positioning the vibrational transducer  
2 comprises introducing a catheter which carries the transducer into the body lumen.

1               15. A method as in claim 14, wherein positioning further comprises  
2 inflating a balloon in the catheter to at least partly engage the luminal wall and locate the  
3 transducer at a pre-determined position relative to the target site.

1               16. A method as in claim 15, wherein the transducer is inside the balloon  
2 and inflating the balloon with an acoustically transmissive material which centers the  
3 transducer within the lumen and enhances transmission of the acoustic energy to the tissue.

1               17. A method as in claim 15, wherein the transducer is located between a  
2 pair of axially spaced-apart balloons and inflating the balloon centers the transducer within  
3 the lumen, further comprising introducing an acoustically transmissive medium between the  
4 balloons to enhance transmission of the acoustic energy to the tissue.

1               18. A method as in claim 15, further comprising moving the transducer  
2 relative to the balloon(s) in order to focus or scan the acoustic energy axially on the luminal  
3 tissue surface.

1               19. A method as in claim 16, wherein the acoustically transmissive  
2 medium is cooled to cool the luminal tissue surface.

1               20. A method as in claim 1, further comprising monitoring temperature at  
2 the luminal tissue surface.

1               21. A method as in claim 1, further comprising monitoring temperature  
2 below the luminal tissue surface.

1               22. A method as in claim 1, wherein energizing comprises focusing the  
2 acoustic energy beneath the luminal tissue surface.

1               23. A method as in claim 1, wherein energizing comprises focusing the  
2 acoustic energy at or just before the luminal tissue surface.

3               24. A method as in claim 27, wherein the vibrational transducer comprised  
4 a phased array.

1               25. A method as in claim 24, wherein the phased array is selectively  
2 energized to focus the acoustic energy at one or more desired locations in the tissue  
3 surrounding the body lumen.

1               26. A method as in claim 1, wherein positioning the vibrational transducer  
2 comprises:

3               introducing a cannula to the target site;  
4               expanding a balloon on the cannula at the target site with an acoustically  
5 transmissive medium; and  
6               selectively directing the vibrational transducer within the balloon to remodel  
7 targeted tissue.

1               27. A method as in claim 26, further comprising viewing the target tissue  
2 through a scope in or on the cannula while directing the vibrational transducer.

1               28. A method as in claim 26, wherein selectively directing comprises  
2 deflecting and/or rotating a beam transducer.

1               29. A method as in claim 26, wherein selectively directing comprises  
2 axially translating a circumferential array transducer.

1               30. A method as in claim 26, wherein selectively directing comprises  
2 everting the transducer to direct energy against tissue surrounding an opening to the body  
3 lumen.

1               31. A method as in claim 30, wherein the balloon is expanded over the  
2 entire opening.

1               32. A method as in claim 31, wherein the balloon is expanded over a  
2 location adjacent to the opening.

1               33. A method as in claim 26, wherein selectively directing comprises  
2 pivoting at least one transducer from a fixed location within the balloon.

1               34. A method as in claim 33, further comprising deflecting at least one  
2 additional transducer from a fixed location within the balloon.

1               35. A method as in claim 26, wherein selectively directing comprises  
2 expanding a second balloon disposed over the vibrational transducer, wherein the second  
3 balloon may be axially translated within the first balloon.

1               36. A method as in claim 1, wherein positioning the vibrational transducer  
2 comprises: expanding a balloon over an opening at one end of the body lumen;  
3               filling the end of the lumen over the balloon with an acoustically transmissive  
4 medium; and  
5               positioning the vibrational transducer within the medium to direct acoustic  
6 energy at the luminal tissue.

1               37. A method as in claim 1, wherein positioning the transducer comprises:  
2               capturing luminal tissue between opposed elements, wherein the transducer is  
3 disposed on one of the elements; and  
4               directing energy from the transducer into the captured tissue.

1               38. A method as in claim 37, wherein capturing comprises clamping with  
2 movable elements.

1               39. A method as in claim 37, wherein capturing comprises applying a  
2 vacuum to the tissue to draw said tissue between the opposed elements.

1               40. A method as in claim 1, wherein the body lumen is the esophagus and  
2 the patient suffers from gastroesophageal reflux disease (GERD).

1               41. A method as in claim 40, wherein the acoustic energy remodels the  
2 tissue surrounding a lower esophageal sphincter.

1                  42. A method as in claim 1, wherein the body lumen is the stomach and  
2 the patient suffers from a hiatal hernia.

1                  43. A method as in claim 42, wherein the acoustic energy remodels the  
2 tissue surrounding a diaphragmatic sphincter.

1                  44. Apparatus for remodeling the lower esophageal sphincter, said  
2 apparatus comprising:

3                      a catheter adapted to be esophageally introduced to the lower esophageal  
4 sphincter (LES); and

5                      a vibrational transducer on the catheter adapted to deliver acoustic energy to  
6 the tissue of the LES in order to lessen gastroesophageal reflux.

1                  45. Apparatus as in claim 44, further comprising an inflatable balloon on  
2 the catheter, wherein said balloon is adapted when inflated to position the catheter within the  
3 LES so that the transducer can deliver energy to the LES.

1                  46. Apparatus as in claim 45 wherein the transducer is positioned coaxially  
2 with the balloon.

1                  47. Apparatus as in claim 45, further comprising means for inflating the  
2 balloon with an acoustically transmissive medium.

1                  48. Apparatus as in claim 45 wherein the transducer is positioned between  
2 a pair of spaced-apart balloons.

1                  49. Apparatus as in claim 44, further comprising means for delivering an  
2 acoustically transmissive medium between the balloons.

1                  50. Apparatus as in claim 44, further comprising means for cooling the  
2 acoustically transmissive medium.

1                  51. Apparatus as in claim 44, further comprising means for measuring  
2 temperature at or beneath the luminal wall.

1                  52. Apparatus as in claim 44, further comprising means to axially translate  
2 the transducer relative to the catheter.

1           53.     Apparatus as in claim 44, wherein the transducer comprises a phased  
2     array.

1           54.     A system comprising:  
2         apparatus as in claim 44; and  
3         a cannula having a channel for receiving and deploying the catheter.

1           55.     A system as in claim 54, further comprising a viewing scope which is  
2     part of or introducable through the cannula.

1           56.     A system as in claim 54, wherein the cannula further comprises an  
2     inflatable balloon over a distal end, wherein the catheter is extendible from the cannula into  
3     the balloon when the balloon is inflated.

1           57.     A system as in claim 56, wherein the vibrational transducer on the  
2     catheter is deflectable and/or rotatable and/or evertable within the balloon when inflated.

1           58.     A system as in claim 56, wherein the vibrational transducer on the  
2     catheter comprises a circumferential array and is axially translatable within the balloon when  
3     inflated.

1           59.     A system as in claim 56, wherein the transducer is pivotally mounted  
2     on the catheter.

1           60.     A system as in claim 56, wherein the transducer is mounted on at least  
2     one of a pair of spaced-apart elements on the catheter configured to receive target tissue  
3     therebetween.

1           61.     A system as in claim 60, wherein the spaced-apart elements are  
2     movable to clamp tissue therebetween.

1           62.     A system as in claim 60, wherein a vacuum source is disposed on the  
2     catheter to selectively draw tissue into the space between the spaced-apart elements.